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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

***DOCUMENT ELECTRONICALLY FILED***

<p>ALBERT L. FELDMAN, Derivatively On Behalf of Nominal Defendant JOHNSON &amp; JOHNSON,</p> <p style="text-align: right;">Plaintiff,</p> <p style="text-align: center;">vs.</p> <p>MARY SUE COLEMAN, JAMES G. CULLEN, MICHAEL M. E. JOHNS, SUSAN L. LINDQUIST, ANNE M. MULCAHY, LEO F. MULLIN, WILLIAM D. PEREZ, CHARLES PRINCE, DAVID SATCHER, WILLIAM C. WELDON and ARNOLD G. LANGBO</p> <p style="text-align: center;">-and-</p> <p>JOHNSON &amp; JOHNSON,</p> <p style="text-align: right;">Nominal Defendant</p>	<p>Civil Action No.:</p> <p style="text-align: center;"><b>VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT</b></p> <p style="text-align: center;"><b>JURY TRIAL DEMANED</b></p>
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Plaintiff Albert L. Feldman (“Plaintiff”), residing at 2868 Camino Serbal, Carlsbad, CA 92009, by his attorneys, submits this Verified Derivative Complaint (the “Complaint”) against the Defendants named herein. The allegations of the Complaint are based on the personal knowledge of Plaintiff as to himself and on information and belief including the investigation of Plaintiff’s counsel, which included a review of filings with the United States Securities and Exchange Commission (“SEC”), as well as press releases and other public statements issued by Johnson & Johnson (“Johnson & Johnson” or the “Company”), and securities analysts’ reports, and other media reports about the Company.

### **NATURE OF THE ACTION**

1. This is a shareholders’ derivative action brought for the benefit of Nominal Defendant Johnson & Johnson against members of its Board of Directors (the “Board”) seeking to remedy Defendants’ breaches of fiduciary duties, and other violations of the law, which have caused substantial losses to Johnson & Johnson and other damages, such as to its reputation and goodwill.

2. The United States Food and Drug Administration (“FDA”) issued a Form 483 inspection report on April 30, 2010 based upon an inspection from April 19, 2010-April 30, 2010 of Johnson & Johnson’s McNeil-PCC, Inc. division in Fort Washington, PA. This plant manufactures children's and infants' liquid medications, which constitute an important part of Johnson & Johnson's business. The Report detailed serious quality and security lapses at the Fort Washington, PA facility and the FDA stated that it is considering a wide range of actions, including possible criminal penalties. Johnson & Johnson has temporarily suspended production

at the plant, which is the Company's only plant that manufactures liquid pediatric drugs, and recalled on April 30, 2010, all of its children's and infant's liquid products because "some of these products may not meet required quality standards." The FDA stated that the recall affects approximately 1500 lots of drugs which were distributed in the U.S. and internationally.

3. Among the observations listed in the Form 483 report was McNeil's failure to initiate "corrective and prevention action" after it had received 46 consumer complaints from June 2009 to April 2010 regarding foreign materials and or dark specks in its drugs. The FDA also cited McNeil for not following quality controls and for not maintaining adequate lab facilities for the testing and approval of components and drug products. The FDA's finding showed that McNeil bought contaminated raw materials from its vendors, which tested positive for a type of bacteria that the FDA has not yet identified.

4. The FDA also found that there were no written procedures to ensure the "identity, strength, quality and purity" that the drugs were represented as having. In addition, the FDA stated that the plant's employees were "not given training in current good manufacturing practices and written procedures required by current good manufacturing practice regulations."

5. Deborah Autor, the FDA's director with the Office of Compliance, said that the FDA met with Johnson & Johnson's senior management in February 2010. She stated: "we expressed serious concerns about McNeil's manufacturing operations and that, even though a routine inspection was scheduled, the February meeting drove us to inspect the plant more quickly."

6. Autor also admonished McNeil for this recall, which she stated was its fourth in the past seven months. She stated: "This is yet another example of when a company has to take full accountability for the quality of its drugs [with] severe consequences for not doing so."

7. The Board of Directors of Johnson & Johnson breached their fiduciary duties of loyalty, care and good faith by failing to exercise attention or oversight in connection with the ongoing operation of the business, as a result of their unconsidered failure to act under circumstances in which due attention would, arguably, have prevented the Company's loss. Demand on the Board of Directors is futile because the directors' conscious inaction constitutes a breach of their duty of good faith, which falls outside the protection of the business judgment rule. Defendants' lack of good faith is established by their sustained and systematic failure to exercise oversight over matters which constituted the core of the Company's business.

8. On behalf of Johnson & Johnson, this action seeks, among other things, damages, and corporate governance reforms.

#### **JURISDICTION AND VENUE**

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because complete diversity exists between the Plaintiff and each Defendant, and the amount in controversy exceeds \$75,000. Plaintiff is a resident of California. Nominal Defendant Johnson & Johnson is a New Jersey corporation with its principal executive offices located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. The other Defendants, as set forth below, are residents of states other than California.

10. This action is not a collusive one to confer jurisdiction that the court would otherwise lack. This Court has supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a).

11. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) because Nominal Defendant maintains offices in this District, a substantial portion of the transactions and wrongs complained of herein, including the Defendants' primary participation in the wrongful acts detailed herein occurred in this District, and Defendants have received substantial compensation

in this District by doing business here and engaging in numerous activities that had an effect in this District.

### **PARTIES**

12. Plaintiff Albert L. Feldman, is and at all times relevant to this action, was a shareholder of Nominal Defendant Johnson & Johnson at the time of the transactions complained of herein and at the time of the misconduct and events complained of herein. He held and holds Johnson & Johnson stock in accounts which he owns or controls, as set forth in the attached Verification. He is a resident of California. His address is 2868 Camino Serbal, Carlsbad, CA 92009. Plaintiff fairly and adequately represents the interests of shareholders who are similarly situated in enforcing the right of the corporation.

13. Nominal Defendant Johnson & Johnson is a New Jersey corporation with its principal executive offices located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. The Company engages in the research, development, manufacture and sale of various products in the health care field worldwide, including liquid infant's and children's Tylenol, Motrin, Zyrtec and Benadryl products. The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices and Diagnostics. The Consumer segment includes nutritional and over-the-counter pharmaceutical products. According to the Company's 2009 Annual Report on Form 10-K, Johnson & Johnson's Consumer segment sales in 2009 were \$15.8 billion, and its Over-the-Counter (OTC) Pharmaceuticals and Nutritionals franchise sales within that segment totaled over \$5.6 billion in 2009.

14. Mary Sue Coleman ("Coleman") has been a member of the Board of Directors since 2003. She is a member of the Science and Technology Advisory Committee. Plaintiff is informed and believes that Defendant Coleman is a resident of Michigan.

15. Defendant James G. Cullen (“Cullen”) has been a member of the Board of Directors since 1995. Plaintiff is informed and believes that Defendant Cullen is a resident of New Jersey.

16. Defendant Michael M. E. Johns (“Johns”) has been a member of the Board of Directors since 2005. He is a member of the Science and Technology Advisory Committee. Plaintiff is informed and believes that Defendant Johns is a resident of Georgia.

17. Defendant Susan L. Lindquist (“Lindquist”) has been a member of the Board of Directors since 2004. She is a member of the Science and Technology Advisory Committee. Plaintiff is informed and believes that Defendant Lindquist is a resident of Massachusetts.

18. Defendant Anne M. Mulcahy (“Mulcahy”) has been a member of the Board of Directors since October 2009. Plaintiff is informed and believes that Defendant Mulcahy is a resident of Connecticut.

19. Defendant Leo F. Mullin (“Mullin”) has been a member of the Board of Directors since 1999. Plaintiff is informed and believes that Defendant Mullen is a resident of Georgia.

20. Defendant William D. Perez (“Perez”) has been a member of the Board of Directors since 2007. Plaintiff is informed and believes that Defendant Perez is a resident of Wisconsin.

21. Defendant Charles Prince (“Prince”) has been a member of the Board of Directors since 2006. Plaintiff is informed and believes that Defendant Prince is a resident of Virginia.

22. Defendant David Satcher (“Satcher”) has been a member of the Board of Directors since 2002 and is Chairman of the Science and Technology Advisory Committee. Plaintiff is informed and believes that Defendant Satcher is a resident of Georgia.

23. Defendant Arnold G. Langbo ("Langbo") has been a member of the Board of Directors since 1991, but did not stand for election in 2010. Plaintiff is informed and believes that Defendant Langbo is a resident of Florida.

24. Defendant William C. Weldon ("Weldon") has been a member of the Board of Directors since 2001 and has been Chairman of the Board, Chief Executive Officer and Chairman of the Executive Committee since 2002. Plaintiff is informed and believes that Defendant Weldon is a resident of Pennsylvania.

25. Together, Defendants Coleman, Cullen, Johns, Lindquist, Mulcahy, Mullin, Perez, Prince, Satcher, Langbo and Weldon shall be collectively referred to as the "Director Defendants." Director Defendants, because of their positions with the Company and access to material nonpublic information available to them, knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public.

#### **DUTIES OF THE DEFENDANTS**

26. By reason of their positions as officers and/or directors of the Company and because of their ability to control the business and corporate affairs of the Company, Defendants owed the Company and its shareholders the fiduciary obligations of good faith, trust, loyalty, candor, and due care, and were and are required to use their utmost ability to control and manage the Company in a fair, just, honest, and equitable manner. Defendants were and are required to act in furtherance of the best interests of the Company and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.

27. Each director and officer of the Company owes to the Company and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the

affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

28. Defendants, because of their positions of control and authority as directors and/or officers of the Company, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

29. To discharge their duties, the officers and directors of the Company were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of the Company were required to, among other things:

- a. exercise good faith in ensuring that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business;
- b. exercise good faith in ensuring that the Company was operated in a diligent, honest and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, including acting only within the scope of its legal authority;
- c. disseminate information truthfully and honestly whenever they communicate with shareholders or the market in general;
- d. establish and maintain an adequate system for gathering and processing information regarding the corporation's business and operations so that upper management and the Board remain informed regarding actual or potential problems; and
- e. when placed on notice of improper or imprudent conduct by the corporation and/or its employees, exercise good faith in taking action to correct the misconduct and prevent its recurrence.

### **SUBSTANTIVE ALLEGATIONS**

#### **A. Current Good Manufacturing Practice ("CGMP") Regulations**

30. CGMP regulations are enforced by the FDA, which defines CGMP as follows:

cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing, processes and facilities. Adherence to the cGMP regulations



assures that identity, strength, quality, and purity of drug products by requiring that manufactures of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures and errors. This assures that drug products meet their quality standards.

31. CGMP regulations are important because a consumer cannot detect through smell, touch or sight, whether a drug product is safe or if it will work.

**B. Johnson & Johnson's McNeil-PCC, Inc. Division Violated CGMP and Other Important Procedures that Would Ensure that Its Products are Safe**

32. The Form 483 report issued by the FDA on April 30, 2010 detailed 20 observations of deficiencies at the McNeil Consumer Healthcare plant in Ft. Washington, PA which manufacturers children's and infant's formulations of Tylenol, Motrin, Zyrtec, and Benadryl.<sup>1</sup>

33. Observation 1 states:

The responsibilities and procedures applicable to the quality control unit are not fully followed:

Specifically,

- a. The Quality Control Unit (QA) authorities most responsible for overseeing daily operations at the Fort Washington facility did not ensure that the responsibilities of the Analytical, Microbiological, Compliance, and Quality Assurance departments were enforced for rejection and withholding from approval any raw material component that contained "known" contamination of gram negative organisms. Raw material (b) (4) (4), lot (b) (4) had known contamination with gram negative organisms and were approved for use to manufacture several finished lots of Children's and Infant's Tylenol drug products, which remain within the expiration date(s) on the market. Responsible firm officials did not adhere to GMP regulations per (b) (4) (4) for (b) (4) (b) (4) in

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<sup>1</sup> The Observations of the Form 483 report are set forth herein as they appeared in the report, including the format of the redactions.

that no Quality Notification was implemented regarding the rejection of contaminated lots of (b) (4) (4)

- b. QA and Compliance Department overall responsibilities per the firm's (b) (4) is deficient as follows: It does not maintain adequate laboratory facilities for the testing and approval (or rejection) of components and drug products; it neglects review and approval of validation protocols regarding changes in product processes and equipment to determine when revalidation is or should be warranted; it is default in investigations, tracking, trending and maintenance of consumer complaint follow-up; and it lacks trending of products, components (i.e., water), and complaints to demonstrate a broad perspective to assure plant conformance with CGMPs.

34. Observations 2 states:

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

Lack of process validation for the manufacture of Infant's Dye-Free Tylenol Suspension Drops, Cherry, Formula (b) (4) 80 mg/0.8 mL. The compounding and transfer of the (b) (4) batch size suspension to the (b) (4) hold tank is not in a "state of control". The firm did not effectively evaluate the change in the manufacturing process (agitation and tank level time to shut off a agitator) when the batch size was increased from (b) (4) into a (b) (4) hold tank and/or when the hold tank size used for a (b) (4) batch was decreased from a (b) (4) to a (b) (4) hold tank.

35. Observation 3 states: "Control procedures fail to include adequacy of mixing to assure uniformity and homogeneity."

36. Observation 4 states: "Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product."

37. Observation 5 states:

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

- a. (b) (4) requires a CAPA (Corrective Action Preventive Action) to be initiated when systemic GMP issues or significant trends have been identified associated with nonconformance events, consumer complaints, manufacturing events and significant trends. The procedure defines a CAPA as a process for ensuring that identified corrective and preventive actions are verified for effectiveness. No CAPA was initiated for the following batches from May 2009 to April 2010 where foreign material, particulate matter and/or contamination were observed...

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- b. No CAPA was initiated for 46 consumer complaints regarding foreign materials, black or dark specks from June 2009 to April 2010.
- c. (b) (4) section (b) (4) requires a (b) (4) metrics review of all new CAPAs, closed CAPAs, CAPAs open for more than (b) (4), and CAPAs exceeding the due date for review. No (b) (4) Metrics for CAPAs was completed.
- d. No CAPA was completed for QN (b) (4) for OOS on (b) (4)

38. Observation 6 states, in part:

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

1. A thorough investigation or any additional analytical testing was not conducted for Infants Dye-Free Tylenol Suspension Drops, Cherry, 80 mg/0.8mL, Formula (b) (4) for the following:
  - a. (b) (4) lots that were super potent and confirmed to fail release specification of (b) (4) Acetaminophen (APAP) assay. For example(s) on End of Run Sample lot #s (b) (4) (b) (4) and (b) (4) (b) (4) is the (b) (4) batch manufactured of the (b) (4) batch campaign following manufacture of the demonstration batch, (b) (4) is the (b) (4) batch of the campaign, and (b) (4) is the (b) (4) batch manufactured. Quality Notification/Investigations (b) (4) rejected these (b) (4) batches based on release testing of end of run samples that failed assay.

- b. The firm's investigation did not extend to the (b) (4) other batches and the demonstration batch of the same drug product associated with the manufacturing change. These (b) (4) batches market. For examples: Lots (b) (4) (b) (4)
- c. As of 04/23/10, no trending was completed to include the (b) (4) batches of the (b) (4) batch campaign manufactured including: (b) (4)

- 2. The firm's investigation into recalls for various Tylenol products containing (b) (4) (b) (4) did not include review of all lots of (b) (4) (b) (4) received from the contract manufacturer between the lot used in manufacture of recalled products (i.e., (b) (4) to the first full lot of (b) (4) (b) (4) received from one entire vendor lot (i.e. (b) (4) McNeil to (b) (4) For examples: Vendor lots (b) (4) (b) (4) Review of these vendor lots found that (b) (4) contained drums contaminated with gram negative organisms. Vendor lot (b) (4) was received on 12/04/08 as receiving lot (b) (4) and on 12/23/08 as receiving lot (b) (4) (b) (4) (b) (4) lots (b) (4) and (b) (4) were used to manufacture the following Tylenol Infant and Children's products which were marketed/distributed and remain within expiration dating as follows...

39. Observation 7 states in part:

GMP training is not conducted with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically, employees are not given training in current good manufacturing practices and written procedures required by current good manufacturing practice regulations as follows...

40. Observation 8 states:

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically,

No review of the batch production and packaging records was conducted for "lack of effect" regarding Infant's Dye Free Tylenol Suspension Drops, Cherry, Lot (b) (4)

Quality Assurance evaluation of complaints documented in Quality Notifications (QNs) (b) (4) (b) (4) determined that no quality issues were warranted and

hence, no manufacturing or packaging investigation was conducted. QN b) (4) regarding the recall of Microcrystalline Cellulose and Carboxymethylcellulose Sodium NF McNeil, lot# b) (4) was associated with this finished product lot b) (4). QN reports regarding lot b) (4) were forwarded from the Corporate Benefits Risk Management group to this manufacturing site for investigation from August to November 2009.

41. Observation 9 states in part: "Each container of component dispensed to manufacturing is not examined by a second person to assure that the weight or measure is correct as stated in the batch records."

42. Observation 10 states in part: "Strict control is not exercised over labeling issued for use in drug product labeling operations."

43. Observation 11 states in part: "There is no written testing program designed to assess the stability characteristics of drug products."

44. Observation 12 states in part:

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Scientific justification does not identify the reason(s) why the firm does not test TSA, a non-selective general microbial growth medium, lot b) (4) during growth promotion tests for microorganisms to include for example, molds, yeasts and other potential known environmental contaminants found in the manufacturing facility and/or raw materials....

45. Observation 13 states in part: "Adequate lab facilities for testing and approval or rejection of components and drug products are not available to the quality control unit."

46. Observation 14 states in part: "Laboratory records do not include complete records of the periodic calibration of laboratory instruments, gauges, and recording devices."

47. Observation 15 states in part: "Written specification for laboratory controls do not include a description of the sampling procedures used."

48. Observation 16 states in part: “Samples taken of in-process materials for determination of conformance to specifications are not representative.

49. Observation 17 states in part: “Each lot of components was not appropriately identified as to its status in terms of being quarantined, approved or rejected.”

50. Observation 18 states in part: “Components are not microscopically examined when appropriate.”

51. Observation 19 states in part: “Records are not kept for the maintenance and inspection of equipment.”

52. Observation 20 states in part: “The persons double-checking the cleaning and maintenance are not dating and signing or initialing the equipment cleaning and use log.”

**C. Johnson & Johnson Has Issued Five Major Product Recalls in the Last Nine Months**

53. Johnson & Johnson has issued five major product recalls in the last nine months.

54. In September 2009, McNeil recalled 21 different pediatric liquid products due to suspected poor quality ingredients. As the Company stated in a September 18, 2009 letter to healthcare professionals:

I am writing to inform you that, in consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare is voluntarily initiating a recall of certain lots of Childrens’ and Infants’ TYLENOL® products that were manufactured between April 2008 and June 2008. The full list of recalled product lots is below.

The company has implemented this recall because examination of bulk raw material detected that one of the inactive ingredients did not meet internal testing requirements. Specially, the gram-negative bacteria *Bukholderia capacia* (B. capacia) was detected.

55. In November 2009, McNeil recalled five lots of its Tylenol Arthritis Pain 100 count with the EZ-open cap product due to reports of an unusual moldy, musty or mildew-like order that led to some cases of nausea.

56. On December 18, 2009, McNeil expanded that recall to include all available product lots of Tylenol Arthritis Pain caplet 100 count bottles with the red EZ-open cap.

57. In January 2010, Johnson & Johnson recalled a line of adult Tylenol pain relievers due to complaints of a moldy smell, which was first reported to McNeil in early 2008. The FDA criticized the Company, stating that it did not respond to the complaints quickly enough, was not thorough in handling the problem and did not inform the FDA promptly. The FDA stated that McNeil knew of the problem in early 2008, but only made a limited investigation. “McNeil should have acted faster,” said Deborah Autor, the director of the FDA’s Office of Compliance of the Center for Drug Evaluation and Research. “When something smells bad, literally or figuratively, companies must aggressively investigate and take all necessary action to solve the problem.” “The company should have acted faster,” Autor said. “All companies have a responsibility to ensure high quality, safety and effectiveness of their products and protect consumers.” The FDA said McNeil first received complaints of an odor in its products in early 2008, but the company did not “identify it as an issue” until September of that year. “McNeil did not report the issue to us until a year later,” Karen Hirshfield, acting branch chief of the FDA’s Recalls and Shortages Branch. The FDA sent McNeil a warning letter for violating manufacturing standards and failing to report and investigate the problem in a timely way, Autor said. Johnson & Johnson had fifteen days to respond and the FDA wanted an explanation as to why the problem was not made public sooner and how they will prevent a re-occurrence of the problem. In the letter, the FDA said it is “concerned” about Johnson & Johnson’s response to the matter.

58. As a result, the FDA met with Johnson & Johnson in February 2010 to discuss manufacturing problems identified in a warning letter about another Johnson & Johnson plant

and decided to step up inspections of the Company's other facilities based on those problems, resulting in the inspection of the Fort Washington plant. Autor stated: "[t]hat warning letter brought us to the point where we thought it was necessary to sit down with management and discuss our concerns."

59. In addition, the Company has recently instituted three additional recalls at the warehouse and retail level:

- a. In March 2010, the Company recalled certain product lots of Childrens' Tylenol® and Childrens' Zyrtec® sold in the United States after determining that the thickness of certain product bottles did not meet standard specifications.
- b. In March 2010, the Company recalled certain product lots of Infants' Tylenol®, Infants' Mortin®, and Childrens' Zyrtec® distributed in the United States after determining that the product lot number and/or expiration date printed on the bottle could become illegible over the life of the product.
- c. In March 2010, the Company recalled Zyrtec® Itchy Eye Drops sold in the United States after determining that certain samples tested did not meet product specifications.

#### **DERIVATIVE AND DEMAND EXCUSED ALLEGATIONS**

60. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress the Defendants' breaches of fiduciary duties and other violations of the law.

61. Plaintiff is currently an owner of Johnson & Johnson common stock and was an owner of Johnson & Johnson common stock continuously during the relevant period.



62. Plaintiff will adequately and fairly represent the interests of the Company and its shareholders in enforcing and prosecuting the Company's rights.

63. As a result of the facts set forth herein, Plaintiff has not made any demand on the Johnson & Johnson to institute this action against Defendants. Such demand would be a futile and useless act because the Board is incapable of making an independent and disinterested decision to institute and vigorously prosecute this action. The Director Defendants face a substantial likelihood of personal liability for the conduct alleged herein, which prevents them from disinterestedly considering a demand by shareholders.

64. Demand is excused because the misconduct complained of herein was not, and could not have been, an exercise of good faith business judgment. As detailed above, the Director Defendants caused, or through a lack of reasonably prudent oversight allowed, the Company to implement inadequate internal controls that continuously and systematically caused Johnson & Johnson's plants, including the McNeil LLP plant, to violate CGMP and result in recalls. While adequate internal controls are important for every organization, it is even more crucial for a company, such as Johnson & Johnson, which manufactures consumer healthcare products for adults and children. Causing or allowing the Company to continuously and systematically lack adequate internal controls is devoid of any legitimate business purpose and is not a product of a valid exercise of business judgment. Accordingly, Defendants' misconduct is egregious enough to reasonably conclude that it falls outside the protection of the business judgment rule, thereby excusing Plaintiff from bringing a pre-suit demand on futility grounds.

65. Moreover, Johnson & Johnson's continuous and systematic failures to correct problems, resulting in five recalls in the last nine months, constitute "red flags," of which the Director Defendants must have known of and recklessly ignored. Additionally, there were 46

serious consumer complaints regarding items concerning the safety of products directed at children and infants, which constituted additional red flags, of which the Director Defendants should have known of and/or recklessly ignored. Moreover, the Company was criticized by the FDA for the prior recall in January 2010 for waiting almost two years to respond to consumer complaints and failing to investigate thoroughly.

66. As detailed above, due to material weaknesses in its internal controls, Johnson & Johnson was forced to make five recalls in a period of nine months. Despite the knowledge of its internal control and manufacturing deficiencies, the Director Defendants did not take the appropriate action to deal with these deficiencies. The magnitude and duration of these “red flags” demonstrate that the failure of the Director Defendants to act accordingly constitutes a lack of good faith and that their actions, or lack thereof, are not protected by the business judgment rule.

**FIRST CLAIM**  
**For Breaches Of The Fiduciary Duties Of Loyalty,**  
**Due Care And Good Faith**  
**(Against All Defendants)**

67. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

68. As alleged herein, Defendants owed and owe Johnson & Johnson fiduciary duties. By reason of their fiduciary relationships, Defendants owed and owe Johnson & Johnson the fiduciary obligations of loyalty, good faith and due care and are required to use their utmost ability to ensure that the Company operates in a fair, just, honest and equitable manner and complies with all laws, rules and regulations. Defendants were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the company.

69. Each of the Defendants knew, or was reckless in not knowing, that each of them violated and breached their fiduciary duties.

70. Each of the Defendants were aware, or should have been aware, of the pervasive problems with Johnson & Johnson's internal and manufacturing controls.

71. As a direct and proximate result of Defendants' failure to perform their fiduciary duties, the Company has suffered significant damages.

72. Defendants are not protected from personal liability by any waiver or exemption from liability clauses because their actions, which were of a continuous and systematic nature were done either intentionally, recklessly, in bad faith, or as a knowing violation of law.

73. Plaintiff, as a shareholder and representative of Johnson & Johnson, seeks damages and other relief for the Company as set forth below.

**SECOND CLAIM  
For Gross Mismanagement  
(Against All Defendants)**

74. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

75. By their actions alleged herein, Defendants abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Johnson & Johnson in a manner consistent with the operations of a publicly held corporation.

76. By their actions, Defendants breached their duties to oversee, direct and control Johnson & Johnson in a manner consistent with the legal duties of directors and officers of a publicly held company and under the applicable state laws.

77. As a direct and proximate result of Defendants' gross mismanagement and breach of duties alleged herein, Johnson & Johnson has sustained significant damages.

**THIRD CLAIM**  
**Waste Of Corporate Assets**  
**(Against All Defendants)**

78. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

79. As a direct result of wrongdoing alleged herein, Defendants have unreasonably and unnecessarily caused Johnson & Johnson to expend substantial corporate funds relating to the recalls to the extreme detriment of the Company.

80. As a direct and proximate result of Defendants' waste of corporate assets as alleged herein, Johnson & Johnson has sustained damages.

**PRAYER FOR RELIEF**

81. WHEREFORE, Plaintiff demands judgment on behalf of Johnson & Johnson as follows:

- A. Against each Defendant for damages in favor of Plaintiff, on behalf of Johnson & Johnson, and awarding punitive and exemplary damages as appropriate, plus pre-judgment interest, modeled in a fashion to ensure Defendants do not participate therein or benefit thereby;
- B. Directing Johnson & Johnson to take all necessary actions to reform and improve its corporate governance and internal control procedures, as well as all other legal requirements to protect the Company and its shareholders from the damaging effects described herein;
- C. Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys', accountants', and experts' fees, costs and expenses;
- D. Granting a trial by jury on all issues so triable; and

E. Granting such other and further relief as this Court may deem just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: May 6, 2010

**LITE DEPALMA GREENBERG, LLC**

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***Counsel for Plaintiff***

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

Plaintiff, by his attorneys, hereby certifies that the matter in controversy is related to *Calamore v. Coleman, et al* Civil Action No. 10-2033 and *Carpenters Pension Fund of West Virginia v. Weldon, et al.*, Civil Action No. 10-2275. Plaintiff is not currently aware of any other party that should be joined in this action.

DATED: May 6, 2010

**LITE DEPALMA GREENBERG, LLC**

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